



UNITED STATES DEPARTMENT OF COMMERCE  
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/205,419	06/10/88	CABILLY	S 100/150C1

EXAMINER

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MARKS IN ART UNIT	PAPER NUMBER
	4

185

DATE MAILED:

03/06/90

*for Restriction Purposes Only*  
☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice re Patent Drawing, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ \_\_\_\_\_

Part II SUMMARY OF ACTION

- ☒ Claims 53-66 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- ☒ Claims 1-52 have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☐ Claims \_\_\_\_\_ are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☒ Claims 53-66 are subject to restriction or election requirement.
- ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).
- ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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Claims 53-66 are pending in the instant application, claims 1-52 having been cancelled by preliminary amendment.

The examiner would like to draw applicant's attention to the patent 4,816,567 which issued from the application SN 483,457- the parent of the instant application. The examiner would like to point out that figures 14 and 15 were not printed in the issued patent. The examiner would greatly appreciate it if applicants<sup>would</sup> please file a certificate of correction to remedy this defect in the patent.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 53-63 and 65-66, drawn to an expression vector, recombinant host cells and methods of making immunoglobulin heavy chains, light chains, Fab regions or heavy and light chains, classified in Class 435, subclasses 235, 320, 172.3, 69.1. and 67.7.

If Group I is elected, an additional election must be made.

Claims 53, 65 and 66 are generic to a plurality of disclosed patentably distinct species as follows:

- a) vectors, transformed hosts and methods of making an immunoglobulin heavy chain in insoluble form,
- b) vectors, transformed hosts and methods of making an immunoglobulin light chain in insoluble form,
- c) vectors, transformed hosts and methods of making an immunoglobulin Fab region in insoluble form,

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d)vectors, transformed hosts and methods of making an immunoglobulin heavy chain AND light chain in insoluble form

e)vectors, transformed hosts and methods of making an immunoglobulin heavy chain in secreted form,

f)vectors, transformed hosts and methods of making an immunoglobulin light chain in secreted form,

c)vectors, transformed hosts and methods of making an immunoglobulin Fab region in secreted form, and

d)vectors, transformed hosts and methods of making an immunoglobulin heavy chain AND light chain in secreted form

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant

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must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the ultimate species of one of these patentably distinct species.

II. Claim 64, drawn to the insoluble particles of proteins produced in transformed E. coli or yeast, classified in Class 530, subclasses 387, and 350 and class 435 subclasses 845, 940 and 70.1.

The inventions are distinct, each from the other because of the following reasons:  
Inventions Group I and Group II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful other than to make the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP section 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a probe and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds

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one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Inventions Group II and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product can be made by another and materially different process such as synthesis in other cell systems. Also the process as claimed can be used to make other and materially different products as exemplified by each of the species of Group I.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

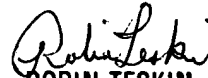
The examiner requests that Applicant submits copies of all of the references cited in the specification. It is requested that Applicant do so at the same time applicant responds to this restriction requirement.

Applicant is reminded that upon the cancellation of claims

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to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication should be directed to Michelle Marks, Ph.D. whose telephone number is 703-557-0909.



ROBIN TESKIN  
EXAMINER  
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